

Overview of Emergency Preparedness (EP) and Physical Environment Requirements

End Stage Renal Disease (ESRD) Facilities

KCER Summit

March 2026

§ 494.62 Condition of participation: EP.

- Original Emergency Preparedness Final Rule (2016)
- Revisions to Emergency Preparedness Requirements: *Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction* (2019)
- Appendix Z covers the Emergency Preparedness requirements and guidance for all 18 impacted providers & suppliers (updated in 2021)
- We also have by-provider checklists developed in partnership with ASPR TRACIE (<https://asprtracie.hhs.gov/cmsrule>)

§ 494.60 Condition: Physical environment.

- The CMS Final Rule for Fire Safety Requirements for Certain Dialysis Facilities published in 2019.
- Appendix H of the SOM covers the core survey process & physical environment requirements.
- EP and Physical Environment are just two of many ESRD regulatory requirements.

Top Cited EP Deficiencies in ESRD Facilities



#1: Dialysis Emergency Equipment



#2: Testing Exercises



#3: EP Training Program

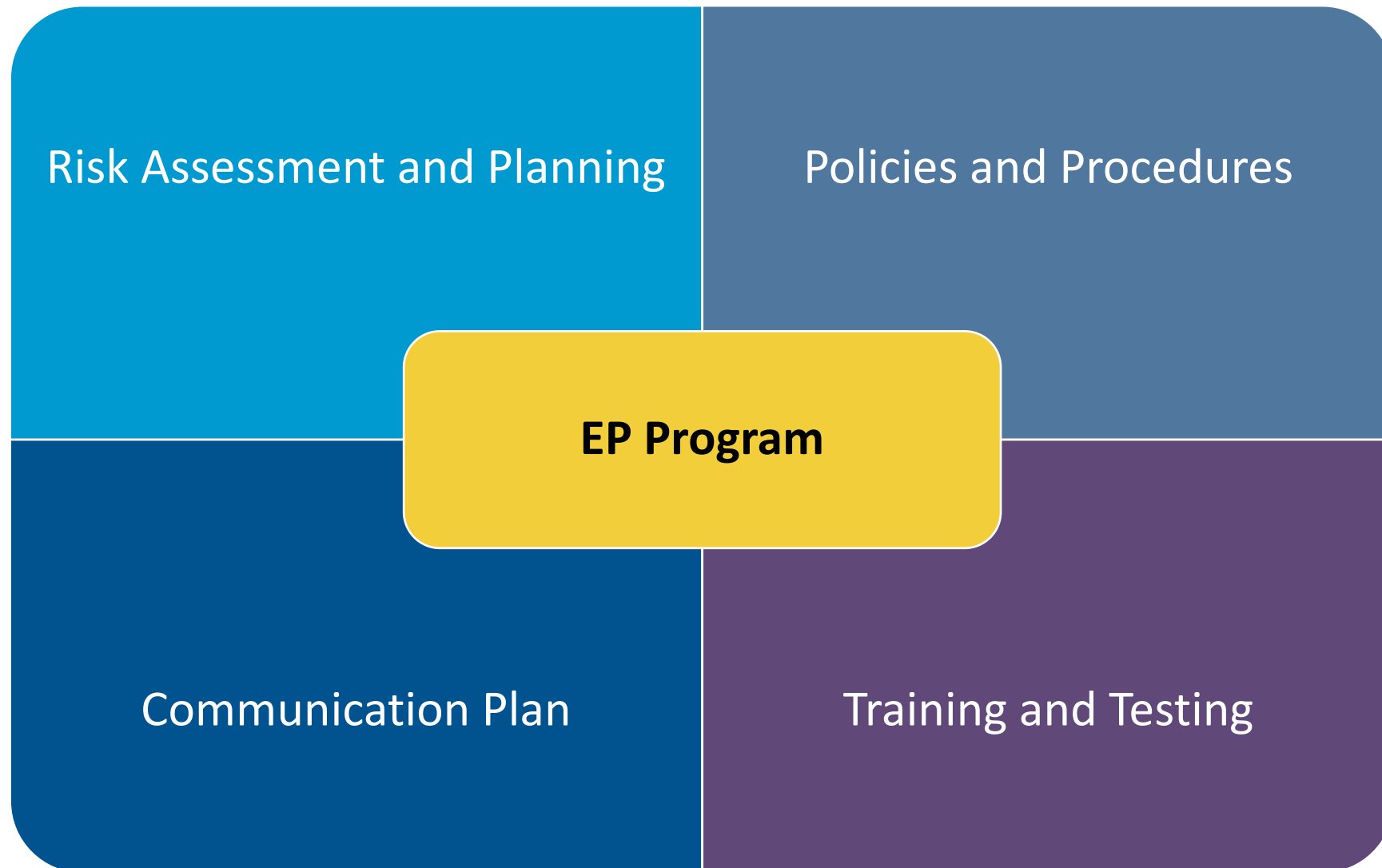


#4: Patient Orientation Program



#5: Training & Testing Program

Four Primary Components



Risk Assessment & Planning

- ▶ Develop an emergency plan based on a **risk assessment**.
- ▶ Perform risk assessment using an “all-hazards” approach, focusing on capacities and capabilities.
- ▶ Facilities must still have a process for cooperation and collaboration with local, tribal (as applicable), regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.
- ▶ Update emergency plan at least every 2 years.

CMS Definition of All-Hazards

- ▶ Focuses on identifying hazards and developing EP capacities and capabilities that can address those as well as a wide spectrum of emergencies or disasters. These include:
 - ▶ Natural, man-made, and or facility emergencies;
 - ▶ Care-related emergencies; equipment and power failures;
 - ▶ Interruptions in communications, including cyber-attacks;
 - ▶ Loss of a portion or all of a facility;
 - ▶ Interruptions in the normal supply of essentials; and,
 - ▶ Emerging infectious diseases.

Risk Assessments & Patient Population

- ▶ General Formula: **Risk = Probability of Hazard x Vulnerability**
- ▶ Factors include:
 - ▶ Historical Occurrence
 - ▶ Probability of Occurrence
 - ▶ Impact
- ▶ Majority of industry templates address these elements mainly from a geographic location perspective.
- ▶ CMS also requires risk assessments & planning to address the **patient population § 494.62(a)(3)**

Considerations for Patient Population

- ▶ Large volume of patients with limited mobility;
- ▶ Different settings & locations;
 - ▶ In-Center
 - ▶ Home Dialysis
 - ▶ Dialysis in a Nursing Home
- ▶ Limited English proficiency

Policies & Procedures (P&P)

- ▶ Develop and implement policies and procedures based on the EP and risk assessment, and the communication plan.
- ▶ Address a range of issues including subsistence needs, evacuation plans, procedures for sheltering in place, tracking patients and staff during an emergency.
- ▶ Review and update policies and procedures at least every 2 years.
- ▶ Plans must be in writing (electronic or paper). Format is at discretion of the facility.

P&P: Dialysis & Emergency Equipment (*Top Cited #1*)

- ▶ The ESRD Facility must have a process by which the staff can confirm that emergency equipment, including, but not limited to, oxygen, airways, suction, defibrillator or automated external defibrillator, artificial resuscitator, and emergency drugs, **are on the premises at all times and immediately available.**
- ▶ Dialysis facilities must be ready to handle care-related emergencies during disasters or emergency situations when emergency medical services may not be immediately accessible.

P&P: Development of Arrangements

- ▶ Policies also must include arrangements with **other dialysis facilities or other providers** to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to dialysis facility patients.
- ▶ Note your patient population (i.e., Patients receiving dialysis in a Nursing Home?)

Communication Plan

- ▶ Develop a communication plan that complies with both Federal and State laws.
- ▶ Coordinate patient care within the facility, across healthcare providers, and with state and local public health departments and emergency management systems.
- ▶ Review and update plan at least every 2 years
- ▶ Appendix Z also provides additional considerations for facility's on reporting occupancy and sharing information with emergency management systems.

Training & Testing Program (*Top Cited #5*)

- ▶ Develop and maintain a training and testing program including initial training in policies and procedures, based on the emergency plan, risk assessment, P&P, and the communication plan.
- ▶ Review and update the training and testing program at least every 2 years.
- ▶ Failure to train staff or conduct testing exercises could result in challenges during a response to an actual emergency event and negatively impact patients receiving care and staff. It also can hinder coordination activities with local and State emergency officials.

Training Program

- ▶ Conduct initial training in EP P&P to all new and existing staff, individuals providing services under arrangement, and volunteers.
- ▶ After initial training, provide emergency preparedness training every 2 years
- ▶ **Demonstrate staff knowledge of emergency procedures.**
- ▶ Maintain documentation of all EP training.
- ▶ **If the EP policies and procedures are significantly updated, conduct training on the updated policies and procedures.**

Deficiencies in Training Program (*Top Cited #3*)

- ▶ Inform staff and patients:
 - ▶ What to do,
 - ▶ Where to go,
 - ▶ Whom to contact, and
 - ▶ **How to disconnect.**
- ▶ Maintain CPR certifications for patient care staff.
- ▶ Train staff on emergency equipment and drugs.

Patient Orientation (*Top Cited #4*)

- ▶ The facility must provide appropriate orientation and training to patients.
- ▶ Driving factor leading to citations is based on training to patients on how to disconnect themselves from the dialysis machine if an emergency occurs.
- ▶ Consider initial training & ongoing training.
- ▶ Quick guides & posting at close reach of the patient.

Testing Requirements

- ▶ Conduct 1 exercise per year (FSE, individual-facility based) and, in alternating years, conduct the exercise of choice (another FSE, individual-facility based or tabletop exercise, mock drill, workshop).
- ▶ If the facility experiences an actual emergency event, the facility is exempt from the **next full-scale exercise, not exercise of choice.**
- ▶ Exercises should alternate various hazards (e.g., not same drill every exercise).

Testing Requirements (Cont.)

- ▶ Exemptions:
 - ▶ For real emergency events, facilities must demonstrate with documentation the activation of the program.
 - ▶ Exemptions only apply to the required full-scale exercise and are based on the established cycle of the facility.
- ▶ All actual emergencies & exercises require an after-action review (AAR).

Deficiencies in Testing Exercises (*Top Cited #2*)

- ▶ Not conducting the appropriate AAR based on real emergency events.
- ▶ Lack of varying testing exercises (reoccurring exercises based on same hazards).

HHS ASPR Technical Resources, Assistance Center, and Information Exchange (TRACIE) Resources

- ASPR TRACIE is a virtual force multiplier supporting health care workers in the field.
- [CMS and Disasters: Resources at Your Fingertips](#)
- [End Stage Renal Disease Facilities Requirements: CMS Emergency Preparedness Final Rule \(Updated\)](#)
- Topic Collections
 - [Communication Systems](#)
 - [Continuity of Operations \(COOP\)/ Business Continuity Planning](#)
 - [Dialysis Centers](#)
 - [Emergency Operations Plans/ Emergency Management Program](#)
 - [Populations with Access and Functional Needs](#)
 - [Training and Workforce Development](#)



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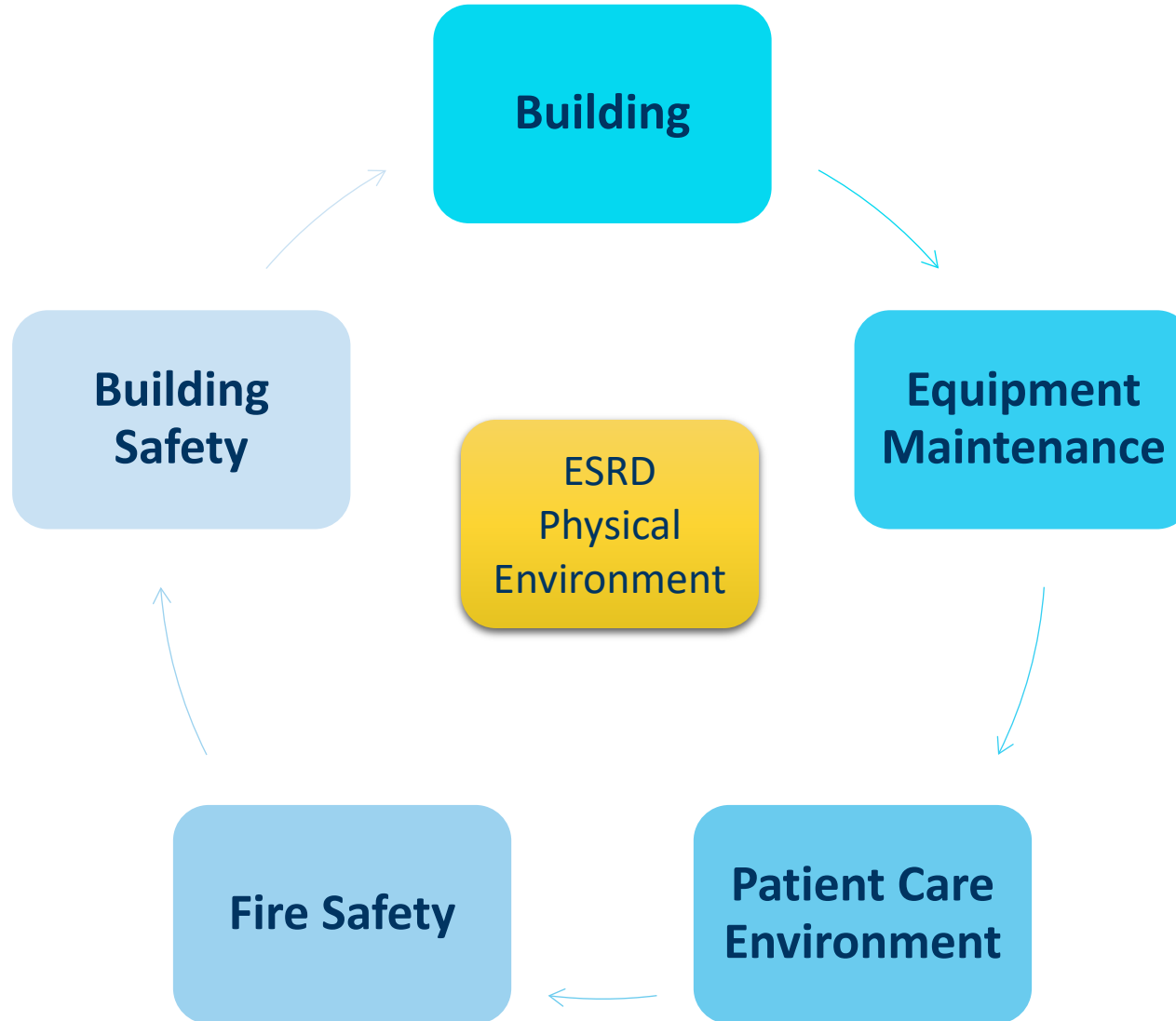


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askasprtracie@hhs.gov

Physical Environment



Building Equipment Maintenance & Patient Care Environment

- Implement and maintain a program ensuring equipment is maintained and operated in accordance with (IAW) manufacturer's recommendations.
- Space for treating patients is:
 - Sufficient for needed care and services.
 - Prevents cross-contamination.
 - Accommodates medical emergency equipment and staff.
- Facility must:
 - Maintain comfortable temperatures.
 - Make reasonable accommodations for patient's comfort and privacy.
 - Ensure patients are in view of staff during treatment.
 - Video does not meet requirement.

Fire Safety

- If one or more exits to outside at ground level are **not** provided from patient treatment area, facility must comply with:
 - NFPA 101, Life Safety Code (LSC), 2012 edition, Ambulatory Health Care Occupancy and Tentative Interim Amendments (TIA) 12-1 through 12-4.
 - Regardless of number of patients served.
- Sprinkler systems required:
 - As of October 14, 2008, for facilities constructed after January 1, 2008.
 - Multi-story building construction Type's II (000), III (200), or V (000), as defined in NFPA 101 21.1.6.1 (Ambulatory Health Care Occupancies).
 - Facilities housed in high rise buildings over 75 feet in height.

Fire Safety (*continued*)

- **May** allow application of State fire and safety code in lieu of LSC if found to adequately protect patients.
- **May** waive provisions of LSC if result in unreasonable hardship and will **not** adversely effect health and safety of patients.
- Facility may **not** operate adjacent to a high hazard area
 - NFPA 99, Health Care Facilities Code (HCFC) Sections 20.1.3.7 and 21.1.3.7 and TIA's 12-2 through 12-6.

Building Safety

- If one or more exits to outside at ground level are **not** provided from patient treatment area, facility must comply with:
 - NFPA 99, Health Care Facilities Code (HCFC), 2012 edition.
 - Regardless of number of patients served.
- NFPA 99, HCFC, Chapters 7, 8, 12, and 13 do **not** apply.
- **May** waive provisions of HCFC if result in unreasonable hardship and will **not** adversely effect health and safety of patients.

Top Deficiency 2024-2025

V-0403. Equipment Maintenance

- § 494.60(b) **Equipment Maintenance.** The dialysis facility must:
 - Implement and maintain a maintenance program.
 - Ensure equipment is maintained and operated IAW manufacturers recommendations.
 - Including:
 - Emergency equipment
 - Dialysis machines and equipment
 - Water treatment system

Points of Contact

Quality, Safety & Oversight EP:

QSOG_EmergencyPrep@cms.hhs.gov

Division of EP and Life Safety (DEPL) mailboxes:

- For general EP-LSC inquiries:
 - EP-LSC@cms.hhs.gov
- For LSC Waiver or FSES requests:
 - LSC-Waiver-FSES@cms.hhs.gov
 - (non-deemed providers-suppliers only)

References

- **Electronic Code of Federal Regulation (eCFR):**

- [§ 494.60 Condition: Physical environment](#)

- [§ 494.62 Condition of Participation: Emergency Preparedness](#)

- **State Operations Manual (SOM):**

- [Appendix H - Guidance to Surveyors: End-Stage Renal Disease Facilities](#)

- [Appendix I - Survey Procedures for Life Safety Code Surveys](#)

- [Appendix Z- Emergency Preparedness for All Provider and Certified Supplier Types Interpretive Guidance](#)

- **National Fire Protection Association (NFPA) Codes:**

- [NFPA 101, Life Safety Code \(LSC\) 2012 edition](#)

- [NFPA 99, Health Care Facilities Code \(HCFC\) 2012 edition](#)

- **[Quality, Safety and Education Portal \(QSEP\)](#)**

- Free public access to the ESRD Survey Training Plan

Thank you!

